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Jennifer M. Duk, Reg No. 52,838

Name of applicant, assignee or
Registered Representative

Jennifer M. Duk

Signature

10.13.04

Date of Signature

Our Case No. 11762-47

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen D. Newman)

Serial No. 10/789,961)

Filing Date: February 27, 2004)

For PACKAGING FOR DISPOSABLE
CONTACT LENSES)

) Examiner

) Group Art Unit No.

**CERTIFIED COPY OF DOCUMENT FOR CLAIM OF PRIORITY
UNDER 35 U.S.C. § 120**

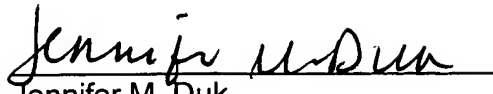
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Dear Sir:

Please find the enclosed certified copy of Australian Provisional Patent Application No. PR7086, filed on August 17, 2001, to which the above referenced U.S. Patent Application claims priority.

Respectfully submitted,

Dated: October 13, 2004

A handwritten signature in black ink, appearing to read "Jennifer M. Duk", written over a horizontal line.

Jennifer M. Duk
Registration No. 52,838
Attorney for Applicant

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IFw

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8

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Date: October 13, 2004 Name: Jennifer M. Duk, Reg. No. 52,839 Signature: Jennifer M. Duk

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GILSON
& LIONE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Stephen D. Newman

Appln. No.: 10/789,961

Filed: February 27, 2004

For: PACKAGING FOR DISPOSABLE SOFT
CONTACT LENSES

Attorney Docket No: 11762/47

Examiner: n/a

Art Unit: 3728

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Attached is/are:

- ☒ Certified Copy of Document For Claim of Priority Under 35 U.S.C. Section 120; Certified Copy of Australian Provisional Patent Application No. PR0007086
☒ Return Receipt Postcard

Fee calculation:

- ☒ No additional fee is required.
☐ Small Entity.
☐ An extension fee in an amount of \$_____ for a _____-month extension of time under 37 C.F.R. § 1.136(a).
☐ A petition or processing fee in an amount of \$_____ under 37 C.F.R. § 1.17(____).
☐ An additional filing fee has been calculated as shown below:

					Small Entity			Not a Small Entity	
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra	Rate	Add'l Fee	or	Rate	Add'l Fee
Total		Minus			x \$9=			x \$18=	
Indep.		Minus			x 44=			x \$88=	
First Presentation of Multiple Dep. Claim					+\$150=			+\$300=	
					Total	\$		Total	\$

Fee payment:

- ☐ A check in the amount of \$_____ is enclosed.
☐ Please charge Deposit Account No. 23-1925 in the amount of \$_____. A copy of this Transmittal is enclosed for this purpose.
☐ Payment by credit card in the amount of \$_____ (Form PTO-2038 is attached).
☒ The Director is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and any patent application processing fees under 37 CFR § 1.17 associated with this paper (including any extension fee required to ensure that this paper is timely filed), or to credit any overpayment, to Deposit Account No. 23-1925.

10.13.04
Date

Respectfully submitted,

Jennifer M. Duk
Jennifer M. Duk (Reg. No. 52,838)



Australian Government

Patent Office
Canberra

I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PR 7086 for a patent by STEVE NEWMAN as filed on 17 August 2001.



WITNESS my hand this
Sixteenth day of July 2004

A handwritten signature in cursive script, reading "J. Billingsley".

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

CERTIFIED COPY OF
PRIORITY DOCUMENT

BEST AVAILABLE COPY

RETORT STYLE PACKING FOR DISPOSABLE SOFT CONTACT LENSES.

BACKGROUND

The present invention relates to contact lens packaging and more particularly relates to an improved economic form of package for a contact lens which satisfies lens packaging criteria including sterility and environmentally sensitive disposability.

PRIOR ART

Soft disposable contact lenses are commonly contained in disposable packages. As packaging adds to the overall cost of the lens it should be made as economically as possible but without compromise to the requisite packaging criteria. The traditional packaging for disposable lenses (both two weekly and daily) consists of a polypropylene "boat" or receptacle for the lens, topped by a multi-layer film of Aluminium, bonding agent and Polyethylene. The boat is filled with isotonic saline and has the lens in situ. The "boat" or blister pack is then autoclaved using steam and pressure to terminal sterility. These blister packs are presented to the patient in boxes of individuals or as multiple blister strips. The key issue here is to be able to present the contact lens to the patient in an aesthetically pleasing package that both satisfies the statutory requirements for sterility and stability and allows the patient to remove the lens safely and easily. The packaging is used only once and is discarded after the lens is removed. This fact obviously creates a cost issue with the lens/package combination. In order to reduce the overall price of the lens to the patient, the cost of the packaging should be kept to an absolute minimum. Due to its inherent disposability the package should also conform to the required ecological requirements and should present the least problematic ecological threat as is possible.

An example of the known contact lens packaging is disclosed in United States patent 5,704,468. That patent teaches a packaging arrangement for the containment in a blister pack of a hydrophilic contact lens in a sterile aqueous solution. The packaging includes a form of stiffening groove or wall elements in flanges of base members of the blister packages housing to facilitate an improved attachment between the base members of the blister package housing the lens and a flexible cover sheet utilized for sealing engagement with the base members while incorporating additional strength to the blister package structures.

United States patent 4,392,569 discloses an asepticizing case for the storage and transport of soft contact lenses wherein each lens is confined on a curved surface in a fluid environment without the direct application of force thereto. The case includes a flexible skirt of having a smaller radius of curvature than that of the lens receiving surface is affixed to the cap to insure the positioning of each lens.

Another packaging arrangement for a hydrophilic contact lens is disclosed in United States patent 5,620,088. The packaging arrangement disclosed houses a contact lens in a sterile aqueous solution. More specifically the arrangement discloses a plurality of disposable hydrophilic contact lenses in a specific number of individual packaging arrangements collectively housed in a box like container so as to provide a specified or essentially measured supply of contact lenses for use by a consumer over a predetermined period of time.

A further packaging for holding a contact lens is disclosed in United States patent 4,691,820 which describes a moulded blister package for storing and dispensing a hydrophilic contact lens. The package comprises a base portion which includes a cavity

surrounded by an outstanding flange and a cover sheet sealed to the flange to enclose the cavity. A portion of the side wall of the cavity is inclined to form a ramp to the flange. The cover sheet may be stripped from the flange to expose the cavity and inclined side wall whereupon the lens is readily removed by sliding up and out of the cavity along the inclined surface.

Another packaging arrangement is disclosed in United States patent 5,823,327 which describes a base member for a blister package for the containment of a contact lens and which includes a planar flange extending outwardly about a cavity for housing the contact lens. A proximate peripheral edge of the flange includes a continuous groove into which there is pressed the material of a flexible cover sheet of the blister package so as to clampingly engage the base member.

Retort packages are also known and one such package is disclosed in United States patent 4,769,261 . That patent teaches a seal layer for use in large institutional sized retort pouches comprising an ABA film structure wherein the A layers are each composed of a blend of a minor amount of an elastomer and a major amount of a polyolefin and the B layer is composed of a blend of a major amount of an elastomer and a minor amount of polyolefin. Retort pouches made with the ABA film structure as the seal layer exhibits improved impact strength.

The prior art does not however teach retort packaging for contact lenses

The known contact lens packages have disadvantages which include the following:

1. The packages are relatively expensive for daily disposable packages. Consumers resist packages which contribute to increased cost of a lens. This will become even more of a problem as the daily disposable market grows and becomes more competitive.
2. Prior art packages are traditionally manufactured from two distinctly different materials which are used to make up a blister which houses the lens. This can lead to sealing problems with an attendant risk of compromised sterility. Over time, a poor sealing blister pack can allow its contents to evaporate and render the pack useless. This could cause stock defects and consequent financial losses to the manufacturer. Correction of the defects would be potentially expensive.
3. Should the patient receive a non sterile lens due to poor or incomplete package sealing, there could be the possibility of that patient being subjected to an eye infection with the risk of ocular compromise and resultant litigation.
4. The size of the packaging is a disadvantage to the disposable lens concept as the patient has to deal with a receptacle which is many times larger than the lens itself. As a result of the polypropylene blister component the individual component is somewhat deeper than the lens from a sagittal perspective and as such does not lend itself to a disposable look. If the patient travels, the lenses can prove to be quite a bulky item.

There is along felt want in the industry to provide an economic, convenient disposable contact lens package without compromise to sterility and utility.

INVENTION

The present invention seeks to ameliorate the problems of the prior art packages by providing an alternative and more economic package but without compromise to the statutory and medical requirements of contact lens packages.

Retort style packaging can offer a solution to these problems as it is a homogenous type of material and is made in one piece. The package consists of identical materials thus far approved by the various regulatory authorities around the world whilst remaining simple in construction.

In its broadest form the present invention comprises:

a contact lens package made from one piece and of one material.

In another broad form the present invention comprises:

a disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made in one piece and of one material. According to a preferred embodiment the lens is contained in a retort package. According to another embodiment the retort package is configured to conform partially or wholly with the contact lens.

In another broad form the present invention comprises:

a disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made in one piece and of one material wherein the package is a pliable and flexible retort package.

According to another embodiment the retort package is configured to conform partially or wholly with the contact lens.

In another broad form the present invention comprises:

a disposable contact lens package for holding at least one contact lens in a sterile aqueous solution; characterized in that the package is made in one piece and of one material wherein the package is a pliable and flexible retort package; wherein the material of said one piece can be folded back on itself to form said package.

According to one embodiment access to a lens in said package is via at least one sealed edge of said package.

In another broad form according to a method aspect, the present invention comprises:

A method of producing a disposable contact lens package comprising the steps of:

- a) taking a single sheet of pliable material;
- b) folding said material back on itself to define an envelope to receive a at least one contact lens;
- c) sealing said envelope which that said contact lens is held in a sterile aqueous solution;
- d) allowing access to said package by splitting or dividing said package along at least one edge.

According to one embodiment the edges of said package may be heat sealed.

According to a preferred embodiment the lens in said aqueous solution floats in said solution inside said package.

DETAILED DESCRIPTION

The present invention will now be described according to a preferred, but non limiting embodiment and with reference to the accompanying illustrations: wherein;

Figure 1 shows a perspective view of a prior art disposable contact lens package.

Figure 2a shows a perspective view of a retort contact lens package with contents open to air according to a preferred embodiment of the invention.

Figure 2b shows a perspective view of a retort package with contents sealed according to preferred embodiment.

Referring to figure 1 there is shown a typical known contact lens package 1 which is formed in two pieces 2 and 3. Typically member 2 will be a preformed blister pack and includes a contour 4 which in whole or in part either conforms to the shape of a lens or provides a recess in which a lens may be placed. This is an expensive package to manufacture with the result that the lens will inevitably be more expensive for the consumer. The package is completed with sealing membrane 5 which mates with flange 6 to effect a sterile seal.

Referring to figure 2a there is shown a perspective view of a retort package 10 according to one embodiment of the invention. Package 10 comprises a one piece flexible membrane which is folded back upon itself to form an envelope which receives a contact lens 11 in an aqueous solution. The wall of the package which is preferably a homogenous material does not necessarily conform to the shape of a lens but rather the lens "floats" in the package. The package maybe formed by folding a material back on itself and sealing the edges to form a sterile envelope. Alternatively, the package could be formed from a homogenous material from two pieces heat sealed along their edges in opposing relationship. Access to the lens is gained by dividing the package along one or more predetermined edges.

The manufacturing of disposable lenses becomes more cost effective as the cost of packaging the lens is reduced and the efficiency of sealing and subsequent sterilising is improved. From the patient's perspective the lens can appeal more as a disposable item, takes up far less space and can be packaged in a more appealing fashion.

This type of packaging especially suits daily disposable lenses as the cost component of this type of packaging is a fraction of that of the traditional blister packing.

The form of this packaging would preferably contain one soft contact lens each. The appropriate art work and statutory information may be printed on the external surfaces in a similar fashion to the current packaging.

The shape and integrity of the lens in this "flat" style packaging is preserved surrounding buffer of saline in the packet. This saline will also act as a safety buffer if the lens packet is subjected to rough or potentially damaging treatment. The current blister form can offer no more protection than a retort package due to the Aluminium anterior surface. In fact this surface can be more easily punctured due to its tightness over the polypropylene "boat". The retort style packaging is inherently soft and can deflect potential punctures by moving with the puncturing object.

Some advantages of the retort style packaging are as follows;

1. More homogenous packaging than present with the attendant improvements in sealing and subsequent sterilising
2. Smaller and slimmer packaging lends itself to disposability. Ideal for travelling.

3. More ecologically sound as there is less material to be disposed of and what is disposed is ecologically friendly.

4. Far more cost effective than current types of packaging thus allowing for a significant reduction in cost of goods.

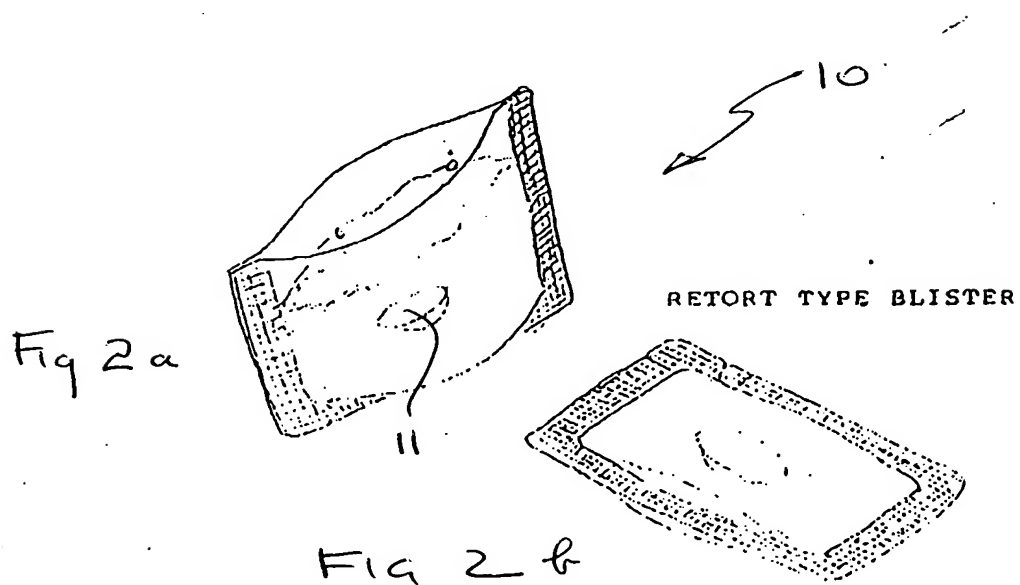
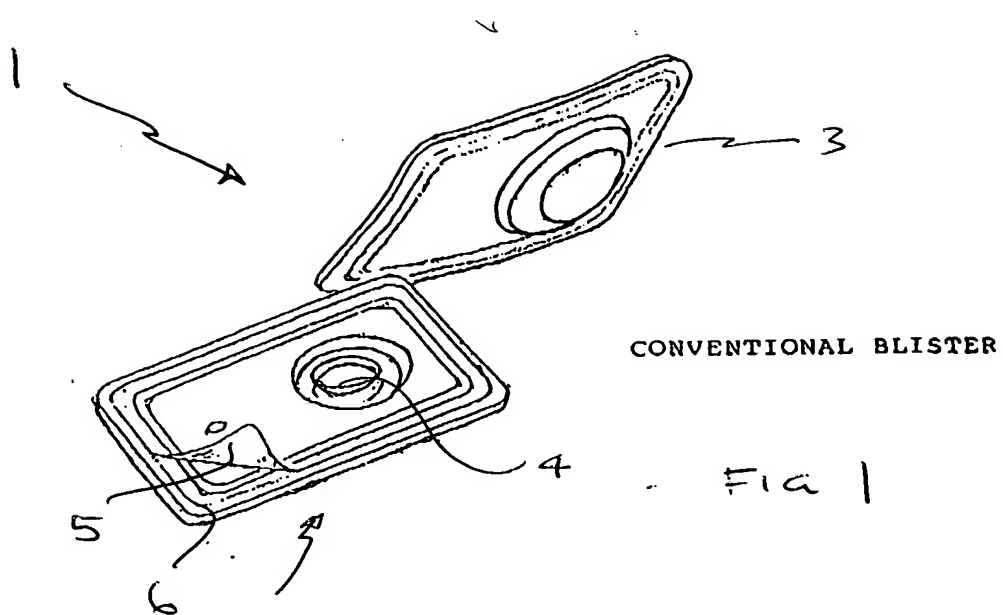
It will be recognized by persons skilled in the art that numerous variations and modification may be made to the invention as broadly described herein without departing from the overall spirit and scope of the invention.

Dated this 17th day of August 2001

STEVE NEWMAN

By their Patent Attorneys

WALSH & ASSOCIATES



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